IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lee *et al.* Atty Dkt No.: 1408.017

Serial No.: Unknown

Deposited as Express Mail: June 15, 2001

Title: TRANSDERMAL PREPARATION CONTAINING HYDROPHILIC OR SALT FORM DRUG

Assistant Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

PRELIMINARY AMENDMENT UNDER 37 CFR 1.115

Dear Sir:

This paper is filed contemporaneously with a filing under 37 CFR 1.53(b). Prior to examination of this application, please amend the specification and claims as follows:

I. In the specification:

A.) Page 1, replace paragraph 1 (line 1) with:

-- Transdermal Preparation Containing Hydrophilic or Salt-form Drug

CLAIM FOR FOREIGN PRIORITY

This application claims foreign priority benefits under 35 USC §119(a) based upon Korean Patent Application Number KR 2000-33330, filed June 16, 2000. The entire contents of the priority application is incorporated herein by reference. --

II. In the claims:

A.) Please replace the text of original claims 1-10 with the following.

1. A transdermal preparation comprising a drug to be delivered through skin, and an adhesive; the drug being hydrophilic or in a salt form, and the adhesive comprising an acrylic polymer including a poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether side chain.

2. The transdermal preparation according to claim 1, further comprising at least one additional component chosen from a solubilizer and a skin permeation enhancer.

3. The transdermal preparation according to claim 1, wherein the amount of drug present in the preparation is in a range of 1-50% by weight, based on the total weight of the preparation.

4. The transdermal preparation according to claim 1, wherein the molecular weight of the poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 100-30000, and wherein the amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether present in the preparation is in a range of 0.01-50% by weight based on the total weight of the preparation.

5. The transdermal preparation according to claim 4, wherein the molecular weight of the poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 400-5000, and wherein the amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether present in the preparation is in a range of 0.05-30 % by weight based on the total weight of the preparation.

6. The transdermal preparation according to claim 1, wherein the drug is selected from a group consisting of sodium, potassium and diethylammonium salts of diclofenac, amfenac, aceclofenac and alclofenac; ketorolac tromethamine; hydrochloride, phosphate and methanesulfonate salts of eperisone and tolperisone; oxybutynin chloride; hydrochloride, hydrobromate, fumarate, succinate and tartrate salts of diphenhydramine, ketotifen, doxylamine, promethazine and trimeprazine; hydrochloride and sulfate salts of tulobuterol, clenbuterol, procaterol and terbutaline; acetate, succinate, valerate and disodium phospate salts of hydrocortisone, dexamethasone and betamethasone; and hydrochloride salts of ondansetron, granisetron and ramosetron.

7. The transdermal preparation according to claim 2, wherein the solubilizer comprises at least one component selected from a group consisting of ethanol, isopropanol, poly(ethylene glycol), ethoxydiglycol, distilled water, propylene glycol, glycerin and dimethylsulfoxide, and wherein the amount of solubilizer present in the preparation is in a range of 0.5-50% by weight based on the total weight of the preparation.

8. The transdermal preparation according to claim 2, wherein the skin permeation enhancer comprises at least one component selected from a group consisting of higher fatty acids; higher alcohols; higher fatty acid esters; fatty acid esters; fatty acid ethers of poly(ethylene glycol); fatty acid esters of poly(ethylene glycol); fatty acid ethers of propylene glycol; fatty acid esters of propylene glycol; sorbitan fatty acid esters; poly(ethylene glycol) sorbitan fatty acid esters; terpenes; sulfoxides; pyrrolidones; amides; and *N*-hydroxy methyl lactate, sorbitol, urea, squalene, olive oil, mineral oil and its derivative, and wherein the amount of skin permeation enhancer present in the preparation is in a range of 0.5-50% by weight based on the total weight of the preparation.

9. The transdermal preparation according to claim 8, wherein the skin permeation enhancer comprises at least one component selected from a group consisting of lauric acid, oleic acid, lauryl alcohol, oleyl alcohol, glycerol monolaurate, glycerol monooleate, polyoxyethylene(2) lauryl ether, polyoxyethylene(2) oleyl ether, propylene glycol monolaurate, propylene glycol monooleate, sorbitan monolaurate, sorbitan monooleate, lauryl diethanolamide, *N*-methyl-2-pyrrolidone and isopropyl myristate.

10. The transdermal preparation according to claim 7, wherein the amount of solubilizer and the amount of skin permeation enhancer present in the preparation are each in a range of 1-30% by weight, based on the total weight of the preparation.

B.) Please add new claims 11-17.

11. The transdermal preparation according to claim 2, wherein the amount of drug present in the preparation is in a range of 1-50% by weight, based on the total weight of the preparation.

12. The transdermal preparation according to claim 2, wherein the molecular weight of the poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 100-30000, and the amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether present in the preparation is in a range of 0.01-50% by weight based on the total weight of the preparation.

13. The transdermal preparation according to claim 2, wherein the drug is selected from a group consisting of sodium, potassium and diethylammonium salts of diclofenac, amfenac, aceclofenac and alclofenac; ketorolac tromethamine; hydrochloride, phosphate and methanesulfonate salts of eperisone and tolperisone; oxybutynin chloride; hydrochloride, hydrobromate, fumarate, succinate and tartrate salts of diphenhydramine, ketotifen, doxylamine, promethazine and trimeprazine; hydrochloride and sulfate salts of tulobuterol, clenbuterol, procaterol and terbutaline; acetate, succinate, valerate and disodium phospate salts of hydrocortisone, dexamethasone and betamethasone; and hydrochloride salts of ondansetron, granisetron and ramosetron.

14. The transdermal preparation according to claim 8, wherein the amount of solubilizer and the amount of skin permeation enhancer present in the preparation are each in a range of 1-30% by weight, based on the total weight of the preparation.

15. The transdermal preparation according to claim 9, wherein the amount of solubilizer and the amount of skin permeation enhancer present in the preparation are each in a range of 1-30% by weight, based on the total weight of the preparation.

16. An adhesive for use in the transdermal delivery of a hydrophilic or salt form drug, the adhesive comprising an acrylic polymer including a poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether side chain.

17. A pharmaceutical dosage form for the transdermal delivery of a hydrophilic or salt form drug, the dosage form comprising an amount of the drug and an adhesive, the adhesive comprising an acrylic polymer including a poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether side chain.

A version of the claims with markings to show the changes made, is provided below.

Version with Markings to Show Changes Made

bold indicates added text / [ ] indicates deleted text

I. In the specification:

A.) Page 1, a paragraph entitled "CLAIM FOR FOREIGN PRIORITY" is added following the title.

II. In the claims:

A.) Claims 1-10 are amended as shown below.

1. (once amended) A transdermal preparation comprising a drug to be delivered through skin , and an adhesive, [which is characterized in that the said] wherein the drug is hydrophilic or in a salt form and the [said] adhesive [has] comprising an acrylic polymer including a poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether [at] side chain.

2. (once amended) The transdermal preparation according to claim 1, [wherein one or more components selected from a group consisting of] further comprising at least one additional component chosen from a solubilizer and a skin permeation enhancer [are further comprised].

3. (once amended) The transdermal preparation according to claim 1 [or 2], wherein the [content of the said] amount of drug present in the preparation is in a range of 1-50% by weight, based on the total weight of the [adhesive layer] preparation.

4. (once amended) The transdermal preparation according to claim 1 [or 2], wherein the molecular weight of the [said] poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 100-30000, and wherein the [content thereof] amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether present in the preparation is in a range of 0.01-50% by weight, based on the total weight of [polymeric adhesive] the preparation.

5. (once amended) The transdermal preparation according to claim 4, wherein the molecular weight of the [said] poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 400-5000, and wherein the [content thereof] amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether present in the preparation is in a range of 0.05-30 % by weight based on the total weight of [polymeric adhesive] the preparation.

6. (once amended) The transdermal preparation according to claim 1 [or 2], wherein the [said] drug is selected from a group consisting of sodium, potassium and diethylammonium salts of diclofenac, amfenac, aceclofenac and alclofenac; ketorolac tromethamine; hydrochloride, phosphate and methanesulfonate salts of eperisone and tolperisone; oxybutynin chloride; hydrochloride, hydrobromate, fumarate, succinate and tartrate salts of diphenhydramine, ketotifen, doxylamine, promethazine and trimeprazine; hydrochloride and sulfate salts of tulobuterol, clenbuterol, procaterol and terbutaline; acetate, succinate, valerate and disodium phospate salts of hydrocortisone, dexamethasone and betamethasone; and hydrochloride salts of ondansetron, granisetron and ramosetron.

7. (once amended) The transdermal preparation according to claim 2, wherein the solubilizer [is] comprises at least one component selected from a group consisting of ethanol, isopropanol, poly(ethylene glycol), ethoxydiglycol, distilled water, propylene glycol, glycerin and dimethylsulfoxide, and wherein the [content is] amount of solubilizer present in the preparation is in a range of 0.5-50% by weight based on [adhesive layer,] the total weight of the preparation.

8. (once amended) The transdermal preparation according to claim 2, wherein the skin permeation enhancer [is] comprises at least one component selected from a group consisting of higher fatty acids; higher alcohols; higher fatty acid esters; fatty acid esters; fatty acid ethers of poly(ethylene glycol); fatty acid esters of poly(ethylene glycol); fatty acid ethers of propylene glycol; fatty acid esters of propylene glycol; sorbitan fatty acid esters; poly(ethylene glycol) sorbitan fatty acid esters; terpenes; sulfoxides; pyrrolidones; amides; and

N-hydroxy methyl lactate, sorbitol, urea, squalene, olive oil, mineral oil and its derivative, and wherein the [content] amount of skin permeation enhancer present in the preparation is in a range of 0.5-50% by weight based on the [adhesive layer] total weight of the preparation.

9. (once amended) The transdermal preparation according to claim 8, wherein the skin permeation enhancer [is] comprises at least one component selected from a group consisting of lauric acid, oleic acid, lauryl alcohol, oleyl alcohol, glycerol monolaurate, glycerol monooleate, polyoxyethylene(2) lauryl ether, polyoxyethylene(2) oleyl ether, propylene glycol monolaurate, propylene glycol monooleate, sorbitan monolaurate, sorbitan monooleate, lauryl diethanolamide, *N*-methyl-2-pyrrolidone and isopropyl myristate.

10. (once amended) The transdermal preparation according to [claims] claim 7 [to 9], wherein the [each content] amount of [the said] solubilizer and [said] the amount of skin permeation enhancer present in the preparation [is] are each in a range of 1-30% by weight, based on the [adhesive layer] total weight of the preparation.

B.) New claims 11-17 are added.

Remarks

Following the addition of new claims 11-17, the application includes claims 1-17. The amendments to original claims 1-10 are as to form only; no new matter has been added.

Applicants respectfully request examination and consideration of claims 1-17.

Respectfully submitted,

Date: June 15, 2001

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